Remarks

Claims 1-3 are pending. By the above amendment, the cross-reference to related applications has been updated on page 1 of the specification and the description at pages 3-4 regarding Figure 3 has been corrected. Claims 1-3 have been amended to more particularly define the invention without the addition of any new matter. Claims 4-10 have been canceled to reduce issues for the Examiner's consideration in the present application.

In the outstanding Office Action, the Examiner objected to the specification, calling for an update of the continuity data. The first paragraph has been updated to reflect the status of the application as a national phase of a PCT application. Consequently, the objection to the specification should be withdrawn.

Claims 1-3 were rejected under 35 U.S.C. 112, first paragraph, as being non-enabled. In making the rejection, the Examiner stated that "the claims lack clarity as having specific and functional utility because no method of treatment has been indicated in the claims . . . ." Considering the Examiner's arguments in support of the rejection, Applicant understands the rejection to be based on the how-to-use prong of Section 112. This rejection is respectfully traversed, as there is no legal requirement that product-type claims themselves recite a specific utility, either under 35 U.S.C. 112, first paragraph, or 35 U.S.C. 101.

The how-to-use prong of the enablement requirement "incorporates as a matter of law the requirement of 35 U.S.C. 101 that the *specification* disclose as a matter of fact a practical utility for the invention." In re Ziegler, 992 F.2d 1197, 1200, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *emphasis added*. See also M.P.E.P. 2107. Since the present specification describes a specific and substantial utility for the invention defined in each of claims 1-3 that is credible, the utility prong of the enablement requirement under 35 U.S.C. 112, first paragraph, has been met even though the claims themselves do not recite such a utility.

Claims 1-10 were also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. More particularly, the Examiner asserted that the claims encompass subject matter not described in the specification in such a way

as to reasonably convey that Applicant had, at the time of filing of the application, possession of the invention. As best understood by Applicant, this rejection is based on the lack of an example in the specification detailing a therapeutic method of administering a specific pharmaceutical formulation to a subject comprising a peptide of SEQ ID NO:1 or SEQ ID NO:2 recited in claims 1-3 to a subject to treat a disease or disorder recited in claims 7-10 and the lack of an *in vivo* showing of effectiveness of such treatment. This rejection is in error.

The written description requirement does not require that a claimed invention be exemplified in the specification by a detailed embodiment. "The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description." M.P.E.P. 2163(II)(A)(1). Moreover, the written description requirement does not require that the utility of a claimed invention be proven by *in vivo* data. In any event, the subject matter of claims 1-3 is adequately supported by the written description in the specification, as those product-type claims are directed to compositions of matter exemplified in the specification, not methods of treatment. Accordingly, the rejection of these claims for supposed failure to meet the written description requirement is erroneous, and should be withdrawn.

The rejections based on prior art should also be withdrawn. Claims 1, 2, 4, 5, and 7-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Ames, Jr. et al. (US 2003/0059856). The Examiner argued in the Office Action that the sequence corresponding to "SEQ ID NO:14 (i.e., residues 28-83) is identical with claimed SEQ ID NO:1 (i.e., residue[s] 1-56)."

Similarly, claims 1, 2, 4, 5, 9, and 10 were rejected under 35 U.S.C. 102(e) as being anticipated by Ferrara et al. (US 2003/0092623). The Examiner asserted that the Ferrara et al. "SEQ ID NO:2 (i.e., residues 28-83) is identical with claimed SEQ ID NO:1 (i.e., residue[s] 1-56)."

The Examiner also rejected claims 1, 3, 4, and 6 under 35 U.S.C. 102(e) as being anticipated by Zhou et al. (US 2003/0235535). The Examiner contended that the Zhou et

al. "SEQ ID NO:8 (i.e., residues 1-56) is identical with claimed SEQ ID NO:2 (i.e., residue[s] 1-56)." These rejections are in error.

Given the lack of identity between the sequence of the entire peptides of the references and the claimed peptides, it appears that the Examiner was interpreting the transitional phrase "consisting essentially of" to be synonymous with the open term "comprising", as SEQ ID NO:14 of Ames Jr., et al. includes amino acid residues not found in the claimed SEQ ID NO:1, SEQ ID NO:2 of Ferrara et al. includes residues not found in the claimed SEQ ID NO:1, and SEQ ID NO:8 of Zhou et al. includes residues not found in the claimed SEQ ID NO:2. To more clearly define the invention, the transitional phrase "consisting essentially of" has been changed to "consisting of" by the above amendment. Since none of the cited references anticipates the instantly claimed invention, as no reference discloses an isolated and purified peptide consisting of the claimed SEQ ID NO:1 or SEQ ID NO:2, and no reference suggests such a peptide, claims 1-3 patentably define over the references.

In light of the foregoing, Applicant respectfully requests allowance of the pending claims.

Respectfully submitted,

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